



BILLING CODE 4120-01-U-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10141, CMS-R-235 and CMS-10515]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice.

Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain . Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of the following:

1. Access CMS' Web Site address at Web Site address at:

[https://www.cms.gov/Regulations-and-](https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html)

[Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html](https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html)

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the *Federal Register* concerning each proposed collection of

information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Prescription Drug Benefit Program; *Use:* Plan sponsor and State information is used by CMS to approve contract applications, monitor compliance with contract requirements, make proper payment to plans, and ensure that correct information is disclosed to potential and current enrollees. *Form Number:* CMS-10141 (OMB control number: 0938-0964); *Frequency:* Annually; *Affected Public:* Private Sector and Business or other for-profit institutions; *Number of Respondents:* 11,771,497; *Total Annual Responses:* 675,231,213; *Total Annual Hours:* 9,261,354. (For policy questions regarding this collection contact Chad D. Buskirk at 410-786-1630)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Data Use Agreement (DUA) Form, Research Identifiable Files Request Packet, and Data Management Plan *Use:* CMS is permitted to disclose data files for approved research purposes in compliance with 45 CFR 164.512(i). Researchers requesting research identifiable files (RIF) must, as part of the request process, complete a research request packet that provides CMS with information pertaining to the research study, including describing how the research results/findings will be disseminated, as well as the data files being requested. Should CMS approve the research request, the data requestor enters into a Data Use Agreement (DUA). This data

collection is necessary to ensure that disclosures of data for research purposes comply with federal laws and regulations as well as CMS policy.

Researchers requesting RIF files also must complete a Data Management Plan Self-Attestation Questionnaire (DMP SAQ). A DMP SAQ is required each time a DUA is established. Both the DUA and the DMP SAQ forms are valid for one year from the date of approval and are renewable at expiration. If the environment described in a DMP SAQ is the same for multiple DUAs from a single organization, the same DMP SAQ can be used across the DUAs, provided it has not expired.

The DMP SAQ is a technical, evidence-based questionnaire that DUA users must complete as part of the data request packet. The DMP SAQ will enable CMS to evaluate researcher data systems to ensure that CMS data are adequately secured and appropriately protected, as per the Privacy Act and the HIPAA Privacy Rule. The DMP SAQ also allows CMS to measure compliance through the implementation of security and privacy controls as outlined in the National Institute of Standards and Technology (NIST) Special Publication 800-53 and the Centers for Medicare & Medicaid Services (CMS) Information Security and Acceptable Risk Safeguards (ARS). The second component of the DMP SAQ is to provide ongoing oversight. All organizations will be subject to routine audits of the environments used to store and process CMS data, as described in their organizational-level DMP SAQ. *Form Number:* CMS-R-235 (OMB control number: 0938-0734); *Frequency:* Occasionally; *Affected Public:* Private Sector, State, Local, or Tribal Governments, Federal Government (Business or for-profits and Not-for-profit institutions); *Number of Respondents:* 9,655; *Total Annual Responses:* 9,655; *Total Annual Hours:* 3,875. (For policy questions regarding this collection, contact Kari A.

Gaare at 410-786-8612.)

3. *Type of Information Collection Request:* Reinstatement of a previously approved collection; *Title of Information Collection:* Payment Collections Operations Contingency Plan; *Use:* Under sections 1401, 1411, and 1412 of the Patient Protection and Affordable Care Act (PPACA) and 45 CFR part 155 subpart D, an Exchange makes an advance determination of tax credit eligibility for individuals who enroll in QHP coverage through the Exchange and seek financial assistance. Using information available at the time of enrollment, the Exchange determines whether the individual meets the income and other requirements for advance payments and the amount of the advance payments that can be used to pay premiums. Advance payments are made periodically under section 1412 of the PPACA to the issuer of the QHP in which the individual enrolls. Section 1402 of the PPACA provides for the reduction of cost sharing for certain individuals enrolled in a QHP through an Exchange, and section 1412 of the PPACA provides for the advance payment of these reductions to issuers. The statute directs issuers to reduce cost sharing for essential health benefits for individuals with household incomes between 100 and 400 percent of the Federal poverty level (FPL) who are enrolled in a silver level QHP through an individual market Exchange and are eligible for advance payments of the premium tax credit. Until January 2016, HHS collected data required to meet these statutory requirements via a manual system in which issuers submitted data. HHS now has an automated system that does not require issuer data submission for FFE issuers. The data collection has been used by HHS to make payments or collect charges from SBE issuers under the following programs: advance payments of the premium tax credit, advanced cost-sharing reductions, and Exchange user fees. The

workbook template was used to make payments in January 2014 and will continue for issuers in states transitioning to a State-Based Exchange, as may be required based on HHS's operational progress. *Form Number:* CMS-10515 (OMB Control Number: 0938-1217); *Frequency:* Occasionally; *Affected Public:* Private Sector - Business or other for-profits and not-for-profit institutions; *Number of Respondents:* 50; *Total Annual Responses:* 600; *Total Annual Hours:* 3,051. (For policy questions regarding this collection contact Christelle Jang at 410-786-8438.)

Dated: April 19, 2022.

William N. Parham III,

Director,

Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

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